

REMARKS

Claims 1-19 were pending in this application. Claim 6 has been canceled.

ARGUMENTS

Applicant respectfully disagrees with the Examiner's statement that the object of the present invention is obvious to one skilled in the art in view of US 2002/0004060 (Heublein et al.) in view of US 6,340,367 (Stinson et al.).

Heublein et al. teaches a medical implant made of biodegradable material comprising 50-98% magnesium, less than 5% of other metals or rare earths, as well as trace amounts of other additions.

Stinson et al. relates to radiopaque markers for implantable stents and discloses two different types of radiopaque markers, namely, retrievable temporary and discrete permanent markers.

It would not have been obvious for a person skilled in the art to combine Heublein et al. and Stinson et al. because, contrary to the Examiner's assertion, these two references do not relate to a similar technical field and difficulty as the present invention. Heublein et al. relates to stent construction with particular biological, mechanical and chemical properties to minimize subsequent foreign-body reaction during the in vivo degradation of the medical implant. Stinson et al. relates to the preparation of implantable radiopaque marker containing radiopaque metallic elements (e.g., titanium) to improve the radiopacity and the localability of endoprostheses during the implantation. Heublein et al. does not disclose, teach or suggest using a radiopaque marker. For this reason, a person skilled in the art would not look to combine the technical features of these two documents to obtain a biodegradable radiopaque marker with a sufficient x-ray visibility according to the present invention.

If a person skilled in the art surprisingly knew Heublein et al., he would not combine the teaching of Heublein et al. and Stinson et al. Heublein et al. shows that a biodegradable material for implantation into the human body, especially a stent, has to fulfill many biological,

mechanical and chemical properties in order to have (a) favorable mechanical properties like elasticity, deformability and stability, (b) a corrosion-resistance within the region of 5 days to 6 months and (c) a permanent biocompatibility of the implant (Heublein et al., paragraph [0013]). A person skilled in the art knows that the properties of the biodegradable metallic material are highly affected by the additional constituents. For example, a person skilled in the art is aware of the formation of local elements in a metallic alloy comprising further metals or rare earth and the thereby induced galvanic corrosion of the biodegradable metallic material. Metallic alloys, especially magnesium alloys are known to have a lower corrosion-resistance in the presence of higher amounts of noble metals or rare earth (e.g., gold or tantalum). Furthermore, this leads to a lack of biocompatibility because, during the corrosion of the magnesium, an increased hydrogen evolution is induced which could lead, in the worst case, to an embolism of the blood vessel. In view of this teaching, a person skilled in the art would not have been motivated to optimize the amount of radiopaque element, as taught by Stinson et al. in the invention of Heublein et al., because a higher percentage of radiopaque elements could decrease the biocompatibility of the implant dramatically.

A person skilled in the art would as well not have found it obvious to combine the teaching of Stinson et al. with Heublein et al. First and foremost, a person skilled in the art would not consider Stinson et al. as the closest prior art. Even though Stinson et al. and the present invention relate to radiopaque markers for medical implants, Stinson et al. discloses in one embodiment a temporary retrievable radiopaque marker which is removed from the device sometime after implantation. Stinson et al. discloses in another embodiment a discrete permanent radiopaque marker made of a non-biodegradable material which is securely attached to the device. Stinson et al. does not disclose, teach or suggest using a biodegradable radiopaque marker. Therefore, a person skilled in the art would not be drawn to Stinson et al. for a solution to the problem.

Even if a skilled person knew Stinson et al, he would not have the motivation to combine the teaching of that document with Heublein et al. In one embodiment, Stinson et al. teaches discrete permanent markers for implantable stents which are used to mark specific locations of features of interest on the stent, for example, the center of the implant (Stinson et al. column 9,

lines 33-41). According to the description, the discrete permanent marker can be constructed using different methods and materials (Stinson et al., column 9, lines 42-55, table 2). For example, the discrete marker can be made of a biocompatible metal wire containing radiopaque metallic elements. Furthermore, the radiopaque metallic elements can be added to different matrix materials like metallic alloys or polymer matrix. All these embodiments have in common that the corresponding discrete permanent marker is not biodegradable in the human body. If a person skilled in the art would have been faced with the task to provide a biodegradable radiopaque marker, he would not consider the teaching of Heublein et al. and use a biodegradable metallic material (e.g., magnesium) as matrix material because this technical feature would be alien for the skilled person to consider. The manufacture of a metallic biodegradable matrix material is rather complex and expensive, particularly if only a few locations on the stents are to be marked. A person skilled in the art would, on this account, search for a more simple and practicable solution and would preferably make his investigation in the field of polymeric materials. It is therefore not obvious for a person skilled in the art to derive the present invention out of Stinson et al. in view of Heublein et al.

US 2003/0153971 (Chandrasekaran et al.) is cited as teaching the use of polylactides, chitosan and hyaluronic acid polymers which, in combination with Heublein et al. and Stinson et al., is stated as rendering Claims 4, 10 and 19 of the present invention obvious. The unique radiopaque marker of the present application has been shown above as being nonobvious over the cited art. The use of these polymers as described in Chandrasekaran et al. does not render the entire invention as claimed obvious as the other aspects of the claimed invention are not obvious.

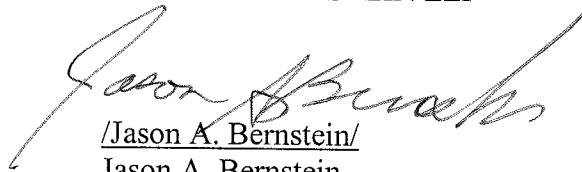
US 2004/0241036 (Meyer-Lindenberg et al.) is cited as teaching the use of yttrium which, in combination with Heublein et al. and Stinson et al., is stated as rendering Claims 8 and 17 of the present invention obvious. The unique radiopaque marker of the present application has been shown above as being nonobvious over the cited art. The use of yttrium as described in Meyer-Lindenberg et al. does not render the entire invention as claimed obvious as the other aspects of the claimed invention are not obvious.

CONCLUSION

Applicant submits that the present application is in condition for allowance and respectfully requests such action. If the Examiner has any questions that can be answered by telephone, please contact the undersigned attorney of record at the telephone number listed below.

Respectfully submitted,

POWELL GOLDSTEIN LLP

A handwritten signature in cursive script, appearing to read "Jason A. Bernstein".

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